

Evaluation of Hearing Status and Eustachian Tube Function in Oral Submucous Fibrosis: A Cross Sectional Study

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ABSTRACT

Introduction

Oral Submucous Fibrosis (OSMF) in severe cases involves palatal and paratubal muscles of Eustachian tube leading to Eustachian tube dysfunction and hearing disabilities. This study aims to evaluate hearing status and Eustachian tube function in patients of Oral Submucous Fibrosis and to correlate them with various groups of the disease.

Materials And Methods

A Cross Sectional study was carried out in a Tertiary Care Hospital on diagnosed patients of OSMF. Patients with hearing loss due to other middle ear pathologies or previous ear surgeries were excluded. Patients were classified into various Groups depending on the severity of the disease. They were subjected to Pure Tone Audiometry and Impedance Audiometry. Results obtained were statistically analysed.

Result

A total of 121 patients (242 ears) were included in the study. On Pure Tone Audiometry, minimal hearing loss was found in 20(8.26%) ears while mild and moderate hearing loss was seen in 26(10.74%) and 28(11.58%) ears respectively. On tympanometry, Type B and Type C tympanograms (abnormal) were seen in 36(14.88) and 26(10.74%) ears, respectively. On Eustachian Tube Function Test, out of 242 ears, 67 ears (27.68%) showed Eustachian tube dysfunction. On using Pearson's chi square test, significant association was found between degree of hearing loss, type of tympanograms and eustachian tube function with various groups of OSMF (p value < 0.05).

Conclusion

OSMF may affect hearing efficiency and Eustachian tube function as the disease progresses.

Keywords

Oral Submucous Fibrosis; Pure Tone Audiometry; Tympanometry; Hearing Loss

Oral Submucous Fibrosis (OSMF) is a chronic disorder characterized by fibrosis of lining mucosa of oral cavity. There is reduction of mouth opening and thickening of mucosa. Incidence of OSMF in India is 0.2% to 1.2% and it is seen more in males compared to females.¹ This condition is more prevalent in Vidharbha region of Maharashtra due to use of specific form of tobacco called Kharra. Also, many other factors such as chewing betel nut, tobacco, smoking and consuming chilies, hypersensitivity, autoimmunity, genetic predisposition and chronic iron

and vitamin B-complex deficiency have been thought to be contributory.^{2,3}

OSMF is predominantly a disease of the oral cavity and Pharynx and characterized by blanching and stiffness

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of the oral mucosa, trismus, burning sensation in the mouth, hypomobility of the soft palate and tongue, loss of gustatory sensation. Occasionally, in advanced cases, it leads to hearing loss due to involvement of palatal and paratubal muscles of Eustachian tube. Histological examination of oral cavity mucosa in OSMF reveals appearance of excessive collagen fibres, constricted blood vessels, oedema and excessive deposition of fibroblasts and infiltration of inflammatory cells.⁴ In severe cases, along with mucosa and submucosa, degenerative changes have been reported in deeper tissues as well including muscle fibres.^{5,6} Since the clinical features are highly characteristic and almost pathognomic, biopsy and histopathological confirmation is not always necessary. Further, there is always a probability that the biopsy may act as an irritant in a form of mechanical trauma and the biopsy site may heal with scar formation due to decreased vascularity and impaired collagen synthesis in the mucosa, which may worsen the disease condition by further limiting the mouth opening.⁷

Although many studies^{3,8-10} have been conducted, reporting the fibrosis and hyalinization in the epithelium of oral cavity and pharynx, only few studies^{4,5} have been reported regarding its effect on Eustachian tube function and hearing status. Aim of the study was to evaluate hearing status and Eustachian tube function in patients of Oral Submucous Fibrosis and to correlate them with various Groups of the disease.

Materials and Methods

A hospital-based Descriptive Cross-Sectional study was carried out at Tertiary Care Hospital from October 1, 2018 to October 31, 2020 after approval from Institutional Ethics Committee. Clinically diagnosed patients of Oral Submucous Fibrosis of any age group and either sex attending ENT OPD and who are willing to participate in the study were included. Patients with hearing loss due to any pathology of middle ear like tympanic membrane perforation, cholesteatoma, ossicular pathologies, external or inner ear pathology and due to trauma to ear, nasopharyngeal mass, cleft palate, cleft lip were excluded from the study. According

to the study by Gupta et al,¹¹ 53 patients of OSMF were studied to assess the Eustachian tube functions by tympanometry. There was a shift in compliance peak (normal) of middle ear in 73.6% patients while in 26.4% patients, there was no shift (dysfunction). Based on this data, the sample size was calculated according to the formula:

$$n = \frac{[DEFF \times Np(1-p)]}{[d^2/Z^2(1-a)^2 \times (N-1) + p \times (1-p)]} = 121.$$

$$DEFF = 1, \alpha=0.05, \beta=0.2, Z=1.96, N=100.$$

So, the sample size was 121 subjects.

After written informed consent from participants, clinical data was obtained that includes demographics, chief complaints, addiction history and history of hearing loss and thorough clinical examination. Patients were examined for inter-incisor distance with Vernier Calliper. Three readings were taken for each individual and the average was recorded as final reading.

To control the inter-examiner and intra-examiner reliability, each step was performed by single examiner. Patients were divided into four groups according to Khanna and Angrade's Clinical classification¹² as follows-

- Group I: Earliest stage without mouth opening limitations with an interincisal distance of >35mm and burning sensation in mouth or acute ulceration.
- Group II: Patients with an interincisal distance of 26-35mm and marble like buccal mucosa, fibrosed areas with normal pink mucosa in between.
- Group III: Moderately advanced cases with an interincisal distance of 15-25mm. Fibrotic bands are visible at the soft palate and anterior pillars of fauces.
- Group IVA: Trismus is severe with an interincisal distance of less than 15mm and extensive fibrosis of all the oral mucosa, tonsils and uvula are also fibrosed and shortened.
- Group IVB: Disease is most advanced with premalignant changes throughout the mucosa.

Audiological assessment was done by using a Pure Tone Audiometer. The frequency tested ranged from 250 to 8000 Hz. Type and degree of Hearing loss was calculated. Hearing impairment was graded into several categories as follows¹³:

- 10-15 dB Normal hearing
- 16-25 dB Minimal hearing loss
- 26-40 dB Mild hearing loss
- 41-55 dB Moderate hearing loss
- 56-70 dB Moderate to Severe hearing loss
- 71-90 dB Severe hearing loss
- >90 dB Profound deafness

Impedance audiometry measured the compliance in the form of a graph. Three types of graphs were obtained amongst which Type A is normal and Type B and C are abnormal suggestive of disease in middle ear. The shift in the compliance peaks at normal, negative and positive pressures were calculated. Shift in compliance peaks indicates that Eustachian Tube function is good and compliance peaks with no shift suggests poorly functioning Eustachian Tube. The data was collected for statistical evaluation.

Statistical analysis was performed using Epi Info Version 7.0 Microsoft Windows. The baseline demographics were presented as Mean, Standard Deviation (SD) and range. Pure Tone Audiometry and Impedance audiometry findings were presented in terms of frequency and percentage. The Pearson Chi-Square test was used to assess the correlation of hearing loss, Eustachian Tube Function with different grades of OSMF. The level of significance was set at 5%.

Results

A total of 121 subjects (242 ears) were included in the study. Age range of study subjects was 18-60 years with a mean age of 35.95 ± 19.09 years. Majority of patients were in 3rd and 4th decade of life (70%) and Male: Female ratio was 4.5:1. Burning sensation in mouth (90.91%) was the most common complaint followed by reduced mouth opening (49.59%) and ulcers in mouth (23.97%). Hard of hearing was reported as associated complaint by 37% patients. Study subjects had addiction of one or more addictive substances. Kharra/Gutkha was the most common substance consumed in 85.12% patients followed by tobacco chewing (64.46%), supari (46.28%) and Pan consumption (34.71%). Mouth opening (Inter-incisor distance) of >35mm was found

in 46.28% patients, while it was 35–26mm in 27.27% patients, 25-15 mm and < 15mm in 18.18% and 08.26% respectively.

Clinically, all patients (121) had involvement of buccal mucosa followed by soft palate in 64(52.89%) patients. Involvement of hard palate was seen in 32(26.45%) patients, anterior pillar in 24(19.83%) patients, uvula and retromolar trigone in 8(6.61%) and 4(3.31%) patients respectively. (Table I)

According to clinical classification of Khanna and Angrade, out of 121 patients, 56(46.28%) belonged to Group I OSMF followed by 33(27.27%) patients in Group II, 22(18.18%) in Group III, 6(4.96%) patients in Group IV A and 4(3.31%) patients in Group IV B. (Table II)

Audiological evaluation was performed in 121 patients (242 ears). Out of 242 ears, hearing level was normal in 168(69.42%) ears, minimal loss in 20(8.26%) ears, while mild and moderate hearing loss was found in 26(10.74%) and 28(11.58%) ears respectively. No patient had severe or profound hearing loss. (Table III) Correlation between Groups of OSMF and degree of hearing loss was evaluated. In Group I OSMF, there was no hearing loss found in ears of any patient. In Group II, 74.24% ears had normal hearing, 19.69% ears had minimal hearing loss, 3.03% and 3.04% had mild and moderate hearing loss. In Group III OSMF, maximum number of ears i.e., 38.64% had mild hearing loss followed by 29.55% ears with moderate and 15.91% with minimal hearing loss. 15.91% ears had normal hearing in Group III patients. In Group IV A OSMF, 8(66.67%) ears had moderate hearing loss and 4(33.33%) ears had mild hearing loss out of 12 ears. In Group IV B, out of 8 ears, 5(62.5%) ears had moderate hearing loss and 3(37.5%) had mild hearing loss. There was statistically significant correlation seen between the Group of OSMF and Hearing loss (Chi-square test, $p < 0.05$). (Table III)

Normal Type A tympanogram was found in 180(74.38%) ears, abnormal Type B curve in 36(14.88%) and Type C curve in 26(10.74%) ears. (Table IV) All subjects belonging to Group I of OSMF (112 ears) had normal i.e., Type A tympanogram. In Group II, 90.91% subjects showed normal Type A tympanogram while

Table I: Distribution of patients of OSMF according to demographic characters and clinical presentation (n=121)

VARIABLES		FREQUENCY (N)	PERCENTAGE (%)
Gender	Male	99	81.82
	Female	22	18.18
	Male: Female	4.5: 1	
Age in Years (Mean \pm SD) in years		35.95 \pm 19.09	
Consumption of Addictive Substances*	Kharra/Gutkha	103	85.12
	Tobacco	78	64.46
	Supari	56	46.28%
	Pan	42	34.71
Inter-incisor Distance in mm	>35	56	46.28
	35-26	33	27.27
	25-15	22	18.18
	<15	10	8.26
Mean \pm SD (in mm)		29.88 \pm 19.09	
Areas of Oral Cavity involved*	BuccalMucosa	121	100
	SoftPalate	64	52.89
	HardPalate	32	26.45
	AnteriorPillar	24	19.83
	Uvula	8	6.61
	RetromolarTrigone	4	3.31

SD- Standard Deviation, * Multiple observations are allowed

Table II: Distribution of study subjects according to Group of OSMF (n=121)

GROUP OF OSMF	FREQUENCY(N)	PERCENTAGE (%)
I	56	46.28
II	33	27.27
III	22	18.18
IVA	6	04.96
IVB	4	03.31
Total Patients	121	100

Table III: Distribution of Ears of patients according to degree of hearing loss in various Groups of OSMF and their correlation (n= 242 ears)

DEGREE OF HEARING LOSS	GROUPS OF OSMF					TOTAL EARS	
	I N (%)	II N (%)	III N (%)	IVA N (%)	IVB N (%)		
Normal	112 (100%)	49 (74.24%)	7 (15.9)	0	0	168 (69.42%)	P value* <0.001
Minimal	0	13 (19.69%)	7 (15.91%)	0	0	20 (8.26%)	
Mild	0	2 (3.03%)	17 (38.64%)	4 (33.33%)	3 (37.5%)	26 (10.74%)	
Moderate	0	2 (3.04%)	13 (29.55%)	8 (66.67%)	5 (62.5%)	28 (11.57%)	
Total Ears	112	66	44	12	8	242	

*Chi- square Test, p value < 0.05 -Statistically significant

6.06% ears showed abnormal Type B and 3.03% subjects showed Type C tympanogram. In Group III, only 18.18% subjects showed normal Type A tympanogram while 54.55% subjects showed abnormal Type B and 27.27% subjects showed Type C tympanogram. In Group IVA, 66.67% and 33.33% subjects showed abnormal Type B and Type C tympanograms, respectively. In Group IVB, Type B and C curve in Tympanometry was seen in

50% of ears each. On correlating tympanometry curves with different groups of Oral Submucous Fibrosis, a significant relation was found between the two.

On Eustachian Tube function test, 67 ears (27.69%) had no shift in compliance peaks meaning poor eustachian tube function while 72.31% ears showed good eustachian tube function (Table 5). All ears (112) of subjects belonging to Group I disease had good

Table IV: Distribution of Ears of patients according to Type of Tympanogram and Groups of OSMF and their correlation (n= 242 ears)

TYPE OF TYMPANOGRAM	GROUPS OF OSMF					TOTAL EARS	
	I N (%)	II N (%)	III N (%)	IVA N (%)	IVB N (%)		
Type A	112 (100%)	60 (90.91%)	8 (18.18%)	0	0	180 (74.38%)	P value* <0.001
Type B	0	4 (6.06%)	24 (54.55%)	4 (66.67%)	4 (50%)	36 (14.88%)	
Type C	0	2 (3.03%)	12 (27.27%)	8 (33.33%)	4 (50%)	26 (10.74%)	
Total	112	66	44	12	8	242 (100%)	

*Chi- square Test, p value < 0.05 -Statistically significant

Table V: Distribution of study ears based on Eustachian tube function in various Groups of OSMF (n=242).

EUSTACHIAN TUBE FUNCTION	GROUPS OF OSMF					TOTAL EARS	P value*
	I N (%)	II N (%)	III N (%)	IVA N (%)	IVB N (%)		
Good	112 (100%)	58 (87.88%)	5 (11.36%)	0	0	175 (72.31%)	<0.001
Poor	0	8 (12.12%)	39 (88.63%)	12(100%)	8 (100%)	67 (27.69%)	
Total	112	66	44	12	8	242	

*Chi- square Test, p value < 0.05 -Statistically significant

Eustachian tube function. 8 ears of Group II, 39 ears of Group III, 12 ears of Group IVA and 8 ears of Group IVB had poor Eustachian Tube function. As the severity of the disease increased, frequency of involvement of Eustachian tube also increased leading to its dysfunction and this was statistically significant correlation. (Table V)

Discussion

OSMF is a chronic progressive disease affecting the oral mucosa and oropharynx. As the disease progresses, there is stiffening of the areas of oral mucosa extending to nasopharynx. Palatal and paratubal muscles like Levator veli palatini, Tensor veli palatini, Tensor tympani and Salpingopharyngeus muscles regulate the patency and function of the nasopharyngeal end of the eustachian tube. When they get affected due to OSMF, it leads to eustachian tube dysfunction, middle ear pressure changes and altered perception of the sound. Labban and Caniff⁶ compared ultrastructural changes in these muscle fibers of the normal individual and OSMF patient and found severe degenerative changes in OSMF patients. Gupta et al¹¹ reported degenerative changes in palatal and paratubal muscle fibers and confirmed extension of fibrosis into the nasopharynx and involvement of the pharyngeal orifice. Rooban et al⁵ also confirmed the fibrosis of nasopharyngeal end of Eustachian tube on the light microscopic study.

In the present study, Oral Submucous fibrosis predominantly affected males of 3rd and 4th decade of life. According to Siddiqui et al¹⁴ and Shah et al,⁸ OSMF

mainly affected second and third decades of life with a male predominance. In the present study, Audiometric evaluation of 242 ears in 121 OSMF patients revealed that hearing was normal in 168 ears (69.42%), minimal conductive hearing loss was present in 20 ears (8.26%), mild conductive hearing loss was present in 26 ears (10.74%), and moderate conductive hearing loss was evident in 28 ears (11.58%). In Shah et al study¹⁵, Pure Tone Audiometry of 60 ears in 30 OSMF patients revealed normal hearing in 42 ears (70%), minimal hearing loss in 5 ears (8.33%), mild hearing loss in 6 ears (10%) and moderate hearing loss was noticed in 7 ears (11.66%). Gupta et al¹¹ found normal hearing in 79.2% of ears, mild to moderate hearing loss was evident in 18.0%, and sensorineural hearing loss was evident in 2.8%. Shah M et al⁸ reported that, out of 54 ears in their OSMF group, hearing was normal in 67%, mild hearing loss was found in 22%, and moderate mixed hearing loss was present in 11%. Our findings were in accordance with those studies. On correlating different groups of OSMF with degree of hearing loss, it was found significant (P value = 0.001). Shah JS et al¹⁵ noticed that, Group III was significantly associated with moderate hearing loss as compared with any other group in both the right and left ears. It was observed that hearing efficiency reduces as the stage of OSMF advances. This was in accordance with studies by Devi P et al,¹⁶ Chandran A et al,¹⁷ Swarup N et al,¹⁸ Chaudhary MS et al¹⁹ and Shah M et al.⁸ In Siddiqui et al study,¹⁴ there was no significant difference ($p=0.088$) found in hearing loss between OSMF and control group on comparison between both the groups.

In the present study, Tympanometry showed normal (Type A) tympanogram in 180(74.38%) ears, abnormal tympanogram i.e., Type B and Type C was seen in 36(14.88) and 26(10.74%) ears, respectively. According to Shah Met al⁸, out of 54 ears examined, normal tympanogram (Type A curve) was recorded in 42 (77.8%) ears. Abnormal tympanograms included type B in none and type C in 12 (22.2%) ears.⁸ In a study done by Gupta SC et al,¹¹ tympanometric evaluation revealed, normal tympanogram (Type A curve) in 80 (75.5%) ears, abnormal tympanogram i.e., Type B curve in 17 (16.0%) and Type C curve in 9 (8.5%) ears out of 108 ears examined. Similar was the finding in Siddiqui et al study.¹⁴ On correlating different stages of OSMF with types of tympanograms, it was found significant (P value = 0.001) in both right and left ears. It was observed that alteration in type of tympanogram occurs as the stage of OSMF advances. This was in accordance with Gupta et al,¹¹ Sowbhagya et al,²⁰ Chandran et al¹⁷ and Shah et al⁸ studies.

In the present study, poor Eustachian tube function was found in 27.69% of the patients of OSMF. On evaluating the correlation between different Groups of OSMF and eustachian tube function, it was found significant with P value <0.001. In Shah et al study⁸ (n=54 ears), Eustachian Tube Function Test (ETFT) revealed no shift in compliance peaks in 15 (27.8%) ears. Gupta SC et al study¹¹ found that, out of 106 ears, ETFT revealed no shift in compliance peaks in 24 (22.7%) ears with 200 daPa pressure changes after swallowing. In a study done by Siddiqui et al,¹⁴ eustachian tube function test revealed a statistically significant difference in eustachian tube function in OSMF patients and controls.

Conclusion

Eustachian tube may be affected in Oral Submucous Fibrosis leading to middle ear pressure changes and hearing impairment. This has clinical and functional significance. Pure Tone Audiometry and Tympanometry Tests are non-invasive, painless Out Patient Department procedures which can be effectively used for early detection of Hearing loss and educating the patient. This will also be helpful in assessing the morbidity and in

identifying the overall prognosis to find more appropriate therapeutic interventions for hearing deficit in order to increase the success rate of treatment. We would suggest that all patients with fibrosis of the oral mucosa should be subjected for Audiological assessment.

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